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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,775

Applicant(s)

TIETZ, RODNEY L.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,5-13 and 21-23 is/are allowed.
- 6) ☐ Claim(s) 2-4, 14-20 and 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1638

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification is withdrawn, in light of the amendment inserting the ATCC accession number of I390186 seed in pages 5, 10, 22, and 29
3. The rejection of claims 1, 3-13, and 15-31 under 35 U.S.C. 112, second paragraph, is withdrawn in light of the claim amendments.
4. The rejection of claims 1-31 under 35 U.S.C. 112, 1<sup>st</sup> paragraph, requiring a deposit of seed of corn variety 1390185, is withdrawn, in light of the deposit of said seed with the ATCC under the requirements of 37 CFR 1.801-1.809, and the written assurance provided in the declaration of deposit received on 21 April 2003.
5. The rejection of claims 1-31 under 35 U.S.C. 102/103 is withdrawn, in light of the claim amendments.

### ***Claim Objections***

6. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

Art Unit: 1638

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form. Claim 26 attempts to limit the plant of claim 25 to be an F1 hybrid corn plant. However, claim 25 is drawn towards corn plants produced by crossing two inbred corn plants, and therefore only encompasses F1 hybrids. Claim 26 then does not further limit the scope of claim 25.

7. Claims 2-4 and 14 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 30 January 2003 under item 2. Applicants traverse the rejection in the paper received 21 April 2003. Applicant's arguments have been fully considered but were not found persuasive.

In response to the rejection of claim 2, Applicant argues that, as with commercial seed, it is not necessary that every seed in a population be identical, that the population may potentially include a small amount of other seed (response, paragraph bridging pages 6-7). However, it remains unclear exactly when a population can only be considered to be a population of I390186 seed and not a population of another seed type. The paragraph bridging pages 5-6 of the specification states that inbred seed "generally" forms at least about 97% of total seed. The term "generally" leaves the definition of population open to encompass any other percentage of inbred seed. The very next sentence indicates that a population of inbred corn seed can contain 15% or less of inbred seed, and this would be indistinguishable from a small fraction, "generally" less than 2% and preferably less than 1% of inbred seed in a population of hybrid seed. If a population contains a greater percentage of seed A than seed B, is this still defined as a population of seed B and not seed A? The discussion of "population" in the specification

Art Unit: 1638

indicates that a population containing 85% of seed A and 15% of seed B can be defined as both a population of seed A and a population of seed B. It is also not clear what is meant by the term "generally" in the context of the definition for "population."

In response to the rejections of claims 3 and 4, Applicant argues that the population of claim 2 may potentially include a small amount of other seed, yet still comprise a population of seed of corn variety I390186 (response, page 7, 2<sup>nd</sup> and 3<sup>rd</sup> full paragraphs). However, it is noted that the definition for "essentially homogeneous populations of inbred seed" on page 5 of the specification includes a broad limitation followed by narrow limitations. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation is considered indefinite, since it does not clearly set forth the metes and bounds of the patent protection desired. Further, the specification does not define "essentially free," making the metes and bounds of claim 4 unclear.

In response to the rejection of claim 14, Applicant argues that while it is true that I390186 seed can only produce I390186 plants, it is not required that a population of plants produced by growing I390186 seeds only contains I390186 plants. To explain this statement, Applicant suggests an example in which a collection of I390186 seed used to plant the population of I390186 plants may contain small amounts of other kinds of seed (response, page 8, 2<sup>nd</sup> full paragraph). However, the claim clearly states that the population of corn plants is produced by growing seed of the corn variety of I390186, not a contaminated collection of I390186 seed. If other types of plants can be produced from I390186 seed, then the very definition of "seed of the corn variety I390186" is brought into question. Claim 14 makes no mention of any other seed. Therefore, the only type of plant that can be in a population of plants

Art Unit: 1638

grown from seed of I390186 is an I390186 plant. It does not matter that some other plant may grow next to an I390186 plant, as I390186 seed did not produce the other plant. Applicant argues that alternatively, other types of unintended plants, such as weeds, may grow within a population of plants that are grown, whether from I390186 seed or another type of seed (response, page 8, 2<sup>nd</sup> paragraph). However, weeds and other non-corn plants are not encompassed. Claim 14 recites, "An essentially homogenous population of corn plants..." (emphasis added).

8. Claims 15-20 and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 15, 17, and 20: the recitation "capable of expressing" in line 1 of claim 15 and line 2 of claims 17 and 20 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claim 15 be replaced with --having--, and in claim 20 with --has--. Similarly, the recitation "is capable of regenerating" in line 2 of claim 17 renders it indefinite. It is suggested that the recitation "the tissue is capable of regenerating plants capable of expressing" be replaced with --plants, when regenerated from said tissue culture, have--.

In claims 16 and 27: the claims broaden the scope of the claims from which they depend. The claims add on a gene and trait to the plant of their parent claims. There is no indication as to how the plants acquired the genes, and the plant of their parent claims does not possess the gene.

In claim 28: the article "a" in the recitation "wherein the single locus was stably inserted into a corn genome" renders the claim indefinite. The recitation does not make clear if the genome is that of I390186 or that of a different corn plant.

9. Claims 2-4, 14, and 24-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 30 January 2003 under item 3. Applicant traverses the rejection in the paper received 21 April 2003. Applicant's arguments were fully considered but were not found persuasive.

In response to the aspect of the rejection concerning the description of non-I390186 seeds in the population and essentially homogenous population of I390186 seeds, Applicant notes that the Office has issued more than 75 patents including claims to populations of corn seed of a given variety, and that the impetus of the instant rejection is therefore not understood. Applicant also argues that the identity of other seed included in a population of I390186 seed is irrelevant, that the fact that the population may be contaminated with other seed hardly takes the claim out of compliance with written description (response, paragraph bridging pages 8-9). However, the allowability of claims in any given patent application is decided based on the fact patterns present within that application, not on the fact patterns of other applications. Further, contrary to what Applicant believes, the other members of a population need to be described, as all members of the population are encompassed by the claim. Applicant continues, arguing that the identity

Art Unit: 1638

of contaminating seeds is irrelevant to the scope of the claim (response, page 9, 1<sup>st</sup> full paragraph). However, as discussed above, the specification appears to indicate that a population that contains 15% of I390186 can still be considered a population of I390186 seed. The other 85% of the population can hardly be considered to be a "contaminant," since they form the majority of seed of the population. Further, "contaminants" have structures and functions that are different from those of I390186.

Regarding claims drawn to hybrid progeny plants and seeds, Applicant argues that the specification provides a detailed description of hybrid 0004411, which was produced with I390186 as one inbred parent, and that the description of this hybrid, along with the fact that any hybrid derived from I390186 will contain half of its genes, is more than adequate to provide a description of hybrid plants and seeds (response, paragraph bridging pages 9-10). Applicant cites *The Regents of The University of California v. Eli Lilly*, and argues that all of the members of the claimed genus of hybrids having I390186 as one parent share the identical structural feature of having the genetic complement of I390186 (response, page 10, 2<sup>nd</sup> full paragraph). However, hybrid 0004411 is just one species of the rather broad genus of all hybrid plants and seeds that can be produced by crossing I390186 to any other corn plant. The morphological and physiological traits of 0004411 are not representative of all of the hybrids encompassed by the claims. That any hybrid plant will inherit half of its genes from I390186 does not provide sufficient information of how those genes or its products will be affected by or interact with the genes and their products inherited from the other parent. The fact that any hybrid plant will inherit half of its genes from I390186 then does not provide sufficient information of the morphological and physiological characteristics expressed by that hybrid plant. The



Art Unit: 1638

specification does not correlate the morphological and physiological traits of 0004411 with the structure of its genes that were inherited from I390186. Single genes do not govern most of the traits of I390186 described in the specification, and so the knowledge that the claimed hybrids have inherited half of their genes from I390186 does not provide any information concerning the morphological and physiological traits of the hybrids. One cannot describe all of the morphological and physiological characteristics of corn plant 0004411 that also definitely will be expressed by other hybrids, nor can one describe the characteristics that will be different. Further, all of the hybrids having I390186 as one parent must also have inherited half of its genes from the other parent. However, descriptions of the other parents are lacking.

Applicant argues that the specification provides an SSR genetic marker profile of I390186 in Table 6, and that because plant I390186 is an inbred all hybrid plants will have these same SSR genetic markers and thus will be genetically distinct and identifiable from any other corn plant (response, page 10, 1<sup>st</sup> full paragraph). However, the presence of these SSR markers does not describe the morphological and physiological traits expressed by the hybrids. None of these markers have been correlated to any expressed traits. Further, Table 6 shows that at least two other corn plants share many of the same loci, and so these shared loci do not distinguish the claimed plants from other plants. It is also noted that the specification does not describe the sequences of the primers that were used to produce this SSR profile, nor the PCR conditions one would need to conduct the experiments. The specification indicates, at the bottom of Table 6, that the primers are from Celera Amgen. However, the sequences of the primers are not described, and it is not clear if these primers are freely available to the public, and if they would remain so for the term of a patent should one issue from the instant application. Further, without

Art Unit: 1638

a description of the sequences of the SSRs, one cannot confirm that the same SSR has been detected.

Applicant also argues, concerning the claimed plants further comprising single locus conversions and transgenes, that they have more than adequately described plants that comprise essentially all of the desired morphological and physiological characteristics of I390186 by way of descriptions of I390186 (response, page 11, 1<sup>st</sup> and 2<sup>nd</sup> full paragraphs). However, the claims broadly encompass the introduction of genes that have not been discovered or isolated. Such genes are clearly not described by the specification. Further, the description of I390186 does not describe the morphological and physiological characteristics of the claimed plants, as the impact that the single locus or transgene has on the plant depends on the product it encodes, and its interaction with other plant products, among other considerations. It is incorrect to generally and simply conclude that a plant having just one extra locus would still essentially have all of the morphological and physiological traits as the same plant without that gene. Applicant also argues that the rejection ignores the methodology for creating single locus conversions and transgenic corn plants, and that single locus traits for conferring male sterility, waxy starch, herbicide resistance, etc. are described (response, page 12, 1<sup>st</sup> paragraph to the paragraph bridging pages 13-14). However, a method of producing a product does not describe the product itself. Applicant argues that every possible single locus conversion does not have to be described (response, paragraph bridging pages 13-14). However, the specification cannot describe genes that have not been discovered. Applicant argues that the specification provides an adequate description of single locus conversion. But the specification does not provide the source where one may obtain all of the genes that are listed in the specification. For example, Applicant's

Art Unit: 1638

response indicates that the specification describes the single locus that confers "yield stability"(response, page 12, 1<sup>st</sup> paragraph). While the specification includes this in a list of single loci, it does not provide the sequences of the loci itself, or an indication that the prior art teaches that they have been isolated at the time the instant invention was filed. For example, a single locus that confers yield stability is not known. It is suggested that the claims drawn towards plants comprising single locus conversions be amended to recite the types of single genes that confer traits contemplated in the specification, for example genes conferring viral resistance, or male sterility, provided the prior art teaches that those types of genes have been isolated and therefore reduced to practice.

Regarding claim 31, Applicant argues that the claim is drawn to a method, the steps of which are recited (response, page 14, 1<sup>st</sup> full paragraph). However, the method requires the use of hybrid plants, which are not described, as discussed above. A method is not described if components required for the method, or the product produced from the method, are not described. The specification does not describe hybrid corn plants, as discussed above, nor inbred corn plants produced from the hybrid plants.

10. Claims 27, 29, and 30 remain and claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 30 January 2003 under

Art Unit: 1638

item 5. Applicant traverses the rejection in the paper received 21 April 2003. Applicant's arguments were fully considered but were not found persuasive.

Applicant argues that the cited references do not have any relevance to corn plants (response, page 15, 4<sup>th</sup> full paragraph). However, the references do raise the issues of the effects linkage disequilibrium, linkage drag, and epistasis when one attempts to transfer a single locus from one plant variety to another. These effects are not limited to just the plants exemplified in the cited references, and Applicant does not explain why these issues are not a concern corn plants. Applicant also argues that the last Office action was incorrect in stating that information of the example of the conversion given in the specification was incomplete, and that the breeding history in that example has seven backcrosses (response, paragraph bridging pages 15-16). However, there is not indication that all of the morphological and physiological traits of the DEKALB proprietary inbred corn plant were recovered, and that only one single locus was transferred from the donor parent. Further, the claims still encompass loci whose functions are unknown. One skilled in the art would not know how to use plants containing such loci. Single loci have also not been identified in the art for all of the traits listed in claim 30, as discussed above.

Claim 28 has been included in this rejection, as the recitation "wherein the single locus was stably inserted into a corn genome by transformation" (emphasis added), does not clearly indicate that it was plant I390186 that was transformed. The claim encompasses the embodiment that another corn plant was transformed, and that the single locus was introduced into I390186 by backcrossing.

Art Unit: 1638

Further, even if claim 28 were directed to plants in which a single locus were transformed directly into I390186, the specification does not enable transforming I390186 cells with all types of transgenes. As broadly interpreted, any type of transgene, encoding any product, could have been introduced into I390186, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). Further, if the effect of transgene expression in I390186 is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. Furtherstill, the effects of transgene expression on the traits expressed by untransformed I390186 are unknown. The specification does not teach one how to use a transformed I390186 plant if all of the morphological and physiological traits of I390186 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

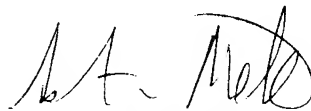
11. Claims 1, 5-13, and 21-23 are allowed. Claims 2-4, 14-20, and 24-31 remain rejected.

Art Unit: 1638

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 23, 2003



ASHWIN D. MEHTA, PH.D  
PATENT EXAMINER